

REMARKS

Claims 1-17 are pending in this application. Of these claims, claims 9-17 have been withdrawn in view of the restriction requirement issued by the Examiner. Claims 1-8 remain. Claim 1 has been amended.

The claims have been rejected under 35 U.S.C § 112, second paragraph, as being indefinite. The Examiner argues that the meaning of the term “hormone steroidal product” used in the claims is unclear. Applicants have reviewed claims 1-8 and do not see where this term appears. Accordingly, applicants believe that this ground of rejection as applied to claims 1-8 is moot.

The Examiner also questions the meaning of the phrase “substantially non-crystalline form” as used in the claims. Claim 1 has been amended to make it clear that substantially all of the steroid hormone present in the product is in non-crystalline form. This corrects the wording of the original claim which created ambiguity as to the physical form of the steroid hormone in the product. Accordingly, applicants believe that this aspect of the rejection issued under § 112, second paragraph, has been addressed.

Finally, the Examiner argues that the use of the term “comprising” renders the claims indefinite since it does not exclude other ingredients from the claimed product. This is not understood since the product may include ingredients other than the positively recited steroid hormone and excipient. These additional components are specifically described in the specification at page 14, lines 18-31, and include, for example, disintegrants, lubricants, colorants, binders, glidants, fillers and other components commonly used in formulating contraceptive and HRT products. Since these ingredients are commonly used in the art and are fully supported by the specification, the claims should not be amended to preclude their inclusion in the claimed steroid hormone product. Accordingly, applicants submit that the § 112, second paragraph, rejection based on the use of the word “comprising” is not well taken and should be withdrawn.

Claims 1-8 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Gast ‘405. The Examiner argues that Gast discloses the combination of trimegestone and lactose. These claims have also been rejected under 35 U.S.C.. § 103(a) as unpatentable over Gast,

since Gast further teaches a hormonal product. Applicants submit that these rejections should be withdrawn since Gast neither teaches nor suggests the claimed invention.

Gast discloses a well-known phasic oral contraceptive including a progestin and an estrogen. The tablet further includes components such as colorants, lubricants, fillers and the excipient lactose. As noted above, all of these additional components are well known in the art of formulating oral contraceptives. Gast nowhere teaches a formulation wherein the steroid hormone in the formulation is in non-crystalline form and wherein the hormone is stabilized in that form by the excipient. Gast simply lists the ingredients that comprise his Example 1 and Example 2 formulations with absolutely no teaching or even a suggestion that these formulations include non-crystalline steroid hormone or that the formulations provide the improved dissolution rate and release rate profiles achieved with the present invention. This is not surprising since Gast is not concerned at all with improved steroid hormone formulations. Gast's objective is to provide a novel tri-phasic regimen for administering oral contraceptives, wherein a combination of an estrogen and a progestin are administered for 23-25 days followed by 3-5 days of estrogen-only administration. Since Gast completely fails to teach or even suggest a steroid hormone product as instantly claimed, applicants submit that the rejections issued under sections 102(b) and 103(a) should be withdrawn.

In view of the foregoing, applicants believe that claims 1-8 are in condition for allowance and respectfully request that a Notice of Allowance directed to these claims be issued at the earliest possible date.

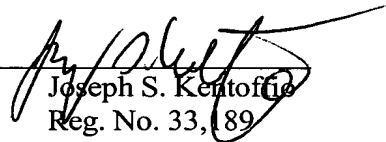
Applicants hereby petition for a one-month extension of time in order to respond to the outstanding Office Action. Please charge the fee of \$110.00 required under 27 C.F.R. § 1.17 (a)(1), and any additional fees that may be required to Deposit Account No. 10-0750/ORT-1548/JSK.

Serial No. 10/022,138

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

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Dated: July 28, 2003